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Attorney's Docket 076936-0307942

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Certificate

FEB 05 2007

of Correction

In re PATENT APPLICATION of:
LORENZO M. LEONI

Confirmation No: 5542

Application No.: 10/779,476

Group Art Unit: 1645

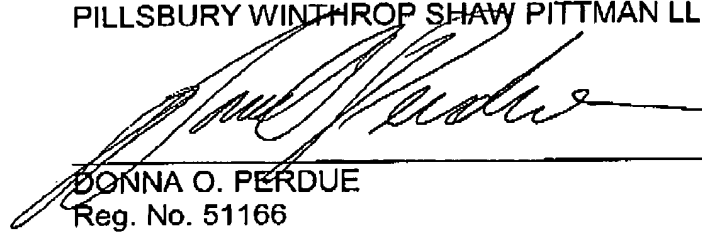
Filed: February 13, 2004

Examiner: Lei Yao, Ph.D.

Title: COMPOSITIONS AND METHODS FOR THE DETECTION AND TREATMENT
OF METHYLTHIOADENOSINE PHOSPHORYLASE DEFICIENT CANCERSCommissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450CERTIFICATION OF FACSIMILE TRANSMISSION
UNDER 37 C.F.R. §1.8I hereby certify that the following papers are being facsimile transmitted
to the Patent and Trademark Office at (571) 273-8300 on the date shown below:

- Request for Expedited Service for Certificate of Correction under 35 U.S.C. §254 and Pursuant to 37 C.F.R. §1.322 (2 pages);
- Certificate of Correction (1 page);
- Exhibit A Supplemental Reply Under 37 C.F.R. §1.111(2) (5 pages);
- Exhibit B Notice of Allowability (2 pages); and
- Exhibit C Interview Summary (1 page).

PILLSBURY WINTHROP SHAW PITTMAN LLP


DONNA O. PERDUE
Reg. No. 51166Date: January 30, 2007
11682 El Camino Real, Suite 200
San Diego, CA 92130-2092
Telephone: (619) 234-5000
Facsimile: (858) 509-4010

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(Certification of Facsimile Transmission--page 1)

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent No: 7,157,551 to LEONI

Application No.: 10/779,476

Confirmation Number: 5542

Filed: February 13, 2004

Group Art Unit: 1645

Issued: January 2, 2007

Examiner: Lei Yao, Ph.D.

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Title: COMPOSITIONS AND METHODS FOR THE DETECTION AND TREATMENT
OF METHYLTHIOADENOSINE PHOSPHORYLASE DEFICIENT CANCERS

Attention: Certificate of Correction Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR EXPEDITED SERVICE FOR CERTIFICATE OF CORRECTION
UNDER 35 U.S.C. §254 AND PURSUANT TO 37 C.F.R. §1.322

Sir:

Patentee hereby respectfully requests expedited service for the attached Certificate of Correction to correct errors in Claim 1 of U.S. Patent No. 7,157,551 ("the '551 patent"). Patentee submits evidence below to show that the error is attributable solely to the Office.

Background

A telephonic Examiner Interview took place on August 2, 2006, between Examiner Yao and Donna Perdue, patentee's attorney of record, concerning proposed amendments to the pending claims. Immediately after the interview, a Supplemental Reply under 37 C.F.R. §1.111(2) was submitted by facsimile directly to the Examiner, memorializing the agreed-upon amendments. (Exhibit A)

A Notice of Allowability with Examiner's Amendment (Exhibit B) and Interview Summary (Exhibit C) were mailed August 11, 2006. The Examiner's Amendment proposed to delete the term "a biological sample" in lines 2-3 of Claim 1, and to cancel Claims 2-8, 11-45, 47-78, and 80, stating that "[a]uthorization for this examiner's amendment was given in a telephonic interview with Donna Perdue and fax on August 2, 2006." (Exhibit B, page 2)

The Examiner's Amendment indicated that claim amendments had been entered

As shown below, the Examiner's Amendment to Claim 1 could only be implemented after Claim 1 had been amended as set forth in the Supplemental Reply. The pending claims discussed during the August 2 interview had been presented by Amendment filed May 17, 2006, in response to a non-final Office Action, and Claim 1 did not contain the phrase "a biological sample." This phrase was first introduced by the amendments to Claim 1 discussed during the interview and memorialized in the Supplemental Reply as follows:

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LEONI - 10/779,476
Attorney Docket: 076936-0307942

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1. An MTAP-binding agent that specifically binds to human methylthioadenosine phosphorylase (MTAP) protein in ~~an embedded~~ a biological sample, wherein said MTAP-binding agent is a monoclonal antibody produced by hybridoma cell line ATCC Accession No. PTA-5001, ~~and wherein said biological sample is not embedded in OCT compound.~~ (Exhibit A, Supplemental Reply, page 2, Proposed Listing of Claims, Claim 1)

Thus, the Examiner's Amendment indicated to the patentee that all the claim amendments in the Supplemental Reply had been properly entered, i.e., the amendments to Claim 1 shown above, as well as the amendments cancelling Claims 2-8, 11-45, 47-78, and 80. The deletion proposed in the Examiner's Amendment was understood to be a further amendment to Claim 1, proposed *sua sponte* by the Office, with the expectation that the Office would also correct the resulting claim informality, to remove the word "in" remaining after the phrase "a biological sample" was deleted.

Claim amendments were not properly entered by the Office

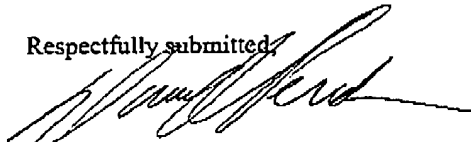
Claim 1 of the '551 patent resulted from partial entry of the amendments presented in the Supplemental Reply, followed by entry of the Examiner's Amendment and failure to correct the resulting claim informality, i.e., only the amendment adding "a" in line 2 was entered, while the amendments deleting the phrases "an embedded" in line 2 and ", and wherein said biological sample is not embedded in OCT compound" in lines 4-5 were not entered, the Examiner's Amendment deleting the resulting phrase "a biological sample" was entered, and the word "in" remaining in line 2 was not deleted. Thus, the present form of Claim 1 of the '551 patent is a result of Office error.

CONCLUSION

Patentee respectfully requests that the evidence presented herein be considered, and a Certificate of Correction to correct Claim 1 be expeditiously issued.

Patentee believes no fees are due. If fees are due, please charge any fees associated with the submission of this paper to Deposit Account Number 033975. The Commissioner for Patents is also authorized to credit any overpayments to the above-referenced Deposit Account.

Respectfully submitted,



Date: January 30, 2007
12255 El Camino Real, Suite 300
San Diego, CA 92130
Fax No. 858.509.4010

PILLSBURY WINTHROP SHAW PITTMAN LLP
DONNA O. PERDUE, Attorney of Record
Reg. No. 51166
Tel. No. 858.509.4093

Attachments: Certificate of Correction
Exhibit A Supplemental Reply
Exhibit B Notice of Allowability with Examiner's Amendment
Exhibit C Interview Summary

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PTO/SB/44 (04-05)

Approved for use through 04/30/2007. OMB 0651-0033

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.
(Also Form PTO-1050)**UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION**Page 1 of 1

PATENT NO. : 7157551

APPLICATION NO.: 10/779,476

ISSUE DATE : January 2, 2007

INVENTOR(S) : LORENZO M. LEONI

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Col. 65, Claim 1, line 2

replace "human methylthioadenosine phosphorylase (MTAP) protein"
with --human methylthioadenosine phosphorylase (MTAP) protein, --.

Col. 65, Claim 1, line 3

replace "in an embedded, wherein said MTAP-binding agent is a"
with --wherein said MTAP-binding agent is a--.

Col. 65, Claim 1, line 4

replace "monoclonal antibody produced by hybridoma cell line"
with --monoclonal antibody produced by hybridoma cell line--.

Col. 65, Claim 1, line 5

replace "ATCC Accession No. PTA-5001, and wherein said biologi-"
with --ATCC Accession No. PTA-5001.--.

Col. 65, Claim 1, line 6

replace "cal sample is not embedded in OCT compound."
with --blank--.

MAILING ADDRESS OF SENDER (Please do not use customer number below):

P. O. Box 10500
McLean, VA 22102

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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Confirmation Report - Memory Send

EXHIBIT A

Page : 001
 Date & Time: 08-02-06 02:16pm
 Line 1 : +858-509-4010
 Line 2 : +
 E-mail :
 Machine ID : PILLSBURY WINTHROP SHAW PITTMAN LLP

Job number : 565
 Date : 08-02 02:15pm
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 Number of pages : 004
 Start time : 08-02 02:15pm
 End time : 08-02 02:16pm
 Pages sent : 004
 Status : OK

Job number : 565

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| | | | |
|------------|--|------------------|----------------|
| Date: | August 2, 2006 | Must Be Sent By: | |
| To: | Examiner Lei Yao, Ph.D. | Fax No: | 371-273-3112 |
| Company: | United States Patent and Trademark Office Art Unit 1642 | Phone No: | 371-272-3112 |
| Confirmed: | | Confirmed By: | |
| From: | Donna O. Perdue Ph.D. | Phone No: | 858.509.4093 |
| User No: | 15268 | C/M No: | 076936-0307942 |
| Comments: | | | |

Dear Examiner Yao

Pursuant to our telephone conversation today, August 2, concerning the claims in this application, please consider the proposed claim amendments presented in the attached Supplemental Reply.

Please call me at (858) 509-4093 to discuss these proposed claim amendments and any other issues relating to this application.

Sincerely

Donna O. Perdue

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 The documents accompanying this facsimile transmission may contain confidential information which is hereby privileged. The information is intended only for the use of the individual or entity named above. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or use of any of the information contained in this transmission is strictly prohibited. If you have received this transmission in error, please immediately notify us by telephone and mail the original transmission to us. Thank you.

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|----------|---|------------------|----------------|
| Date: | August 2, 2006 | Must Be Sent By: | |
| To: | Examiner Lei Yao, Ph.D. | Fax No: | 571-273-3112 |
| Company: | United States Patent and Trademark Office Art Unit 1642 | Phone No: | 571-272-3112 |
| Confirm: | | Confirmed By: | |
| From: | Donna O. Perdue Ph.D. | Phone No: | 858.509.4093 |
| User No: | 15268 | C/M No: | 076936-0307942 |

Comments:

Dear Examiner Yao

Pursuant to our telephone conversation today, August 2, concerning the claims in this application, please consider the proposed claim amendments presented in the attached Supplemental Reply.

Please call me at (858) 509-4093 to discuss these proposed claim amendments and any other issues relating to this application.

Sincerely

Donna O. Perdue

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In re PATENT APPLICATION of: LORENZO Confirmation Number: 5542

M. LEONI

Application No.: 10/779,476

Group Art Unit: 1642

Filed: February 13, 2004

Examiner: Lei Yao, Ph.D.

Title: COMPOSITIONS AND METHODS FOR THE DETECTION AND TREATMENT OF
METHYLTHIOADENOSINE PHOSPHORYLASE DEFICIENT CANCERS

SUPPLEMENTAL REPLY UNDER 37 C.F.R. §1.111(2)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to a telephone conference with Examiner Yao on August 2, 2006,
regarding the claims filed in the above-identified application on May 19, 2006, Applicant
requests consideration of the proposed claim amendments as follows:

Proposed amendments to the claims are reflected in the Proposed Listing of Claims
beginning on page 2 of this paper; and

Remarks begin on page 3.

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**RECEIVED
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1. (Currently amended) An MTAP-binding agent that specifically binds to human methylthioadenosine phosphorylase (MTAP) protein in ~~an embedded a~~ biological sample, wherein said MTAP-binding agent is a monoclonal antibody produced by hybridoma cell line ATCC Accession No. PTA-5001, ~~and wherein said biological sample is not embedded in OCT compound.~~

2-8. (Cancelled)

9. (Original) A hybridoma cell line that produces a monoclonal antibody that specifically binds to human MTAP protein, wherein said cell line has ATCC Accession No. PTA-5001.

10. (Original) A monoclonal antibody which specifically binds to human MTAP, wherein said monoclonal antibody is produced by a cell line ATCC Accession No. PTA-5001.

11-45. (Cancelled)

46. (Previously presented) A kit for determining whether an embedded biological sample contains human MTAP protein comprising: (a) an MTAP-binding agent that specifically binds with an embedded human MTAP protein to form a binding complex; and (b) an indicator capable of signaling the formation of said binding complex, wherein said MTAP-binding agent is a monoclonal antibody produced by the hybridoma cell line ATCC PTA-5001.

47-78. (Cancelled)

79. (Original) Functional antigen binding fragments of a monoclonal antibody secreted by ATCC Accession No. PTA-5001.

80. (Cancelled)

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REMARKS

Claims 1, 6-10, 46, 51, 52, 61, 66, 67, 72-76, and 79 are currently pending. Claims 6, 7, 8, 51, 52, 61, 66, 67, and 72-76 have been cancelled. Claim 1 is currently amended. Thus, Claims 1, 9, 10, 46, and 79 are currently presented for examination.

Proposed Claim 1 is amended pursuant to a telephone conversation between the Examiner and the Attorney of Record on August 2, 2006. The proposed amendment does not introduce new matter.

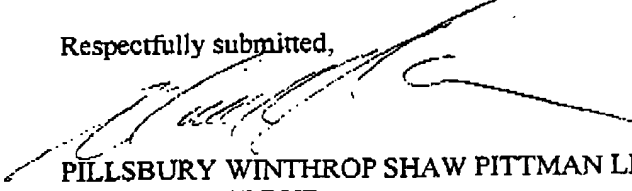
CONCLUSION

Claims 1, 6-10, 46, 51, 52, 61, 66, 67, 72-76, and 79 are currently pending. Claims 6, 7, 8, 51, 52, 61, 66, 67, and 72-76 have been cancelled. Claim 1 is currently amended. Applicant submits that Claims 1, 9, 10, 46, and 79 currently presented for consideration are in condition for allowance.

Applicants believe that no fees are due in connection with the present Supplemental Reply. If any fees are due, please charge any fees associated with the submission of this paper to Deposit Account Number 03-3975. The Commissioner for Patents is also authorized to credit any overpayments to the above-referenced Deposit Account.

The Examiner is encouraged to contact the Attorney of Record at the number listed below to discuss the proposed claim amendments and any other issues relating to the present application.

Respectfully submitted,


PILLSBURY WINTHROP SHAW PITTMAN LLP
DONNA O. PERDUE
Reg. No. 51166
Tel. No. 858.509-4093
Fax No. 858.509-4010

Date: August 2, 2006
11682 El Camino Real, Suite 200
San Diego, CA 92130-2092
(619) 234-5000

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EXHIBIT B**Notice of Allowability**

Application No.

10/779,476

Examiner

Lei Yao, Ph.D.

Applicant(s)

LEONI, LORENZO M.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Telephone communication with Donna Perdue on 8/2/06.

2. ☒ The allowed claim(s) is/are 1, 9, 10, 46 and 79.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.

(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)

2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 1/13/05, 10/11/05

4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

5. ☐ Notice of Informal Patent Application (PTO-152)

6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 8-2-06

7. ☒ Examiner's Amendment/Comment

8. ☐ Examiner's Statement of Reasons for Allowance

9. ☐ Other _____

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Application/Control Number: 10/779,476

Art Unit: 1642

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JAN 30 2007

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted not later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Donna Perdue and fax on August 2, 2006.

The application has been amended as follows:

- 1) In claim 1, delete "a biological sample" in line 2-3.
- 2) Cancel claims 2-8, 11-45, 47-78, and 80.

The following is an examiner's statement of reasons for allowance: The prior art does not anticipate or suggest the novel monoclonal antibody produced by hybridoma cell line ATCC accession qNo, PTA-5001.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.
Examiner
Art Unit 1642


JEFFREY SIEW
SUPERVISORY PATENT EXAMINER

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| | | | |
|--|-------------------------------|-----------------------------------|--|
| EXHIBIT C Interview Summary | Application No. 10/779,476 | Applicant(s) LEONI, LORENZO M. | |
| | Examiner Lei Yao, Ph.D. | Art Unit 1642 | |

All participants (applicant, applicant's representative, PTO personnel):

(1) Lei Yao, Ph.D. (3) _____

(2) Donna Perdue (4) _____

Date of Interview: 02 August 2006.

Type: a) ☒ Telephonic b) ☐ Video Conference
 c) ☐ Personal (copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.
 If Yes, brief description: _____

Claim(s) discussed: 1,6-10,46,51,52,66,67,72-76,79 and 81.


Identification of prior art discussed: _____

Agreement with respect to the claims f) ☒ was reached. g) ☐ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicants decide to cancel the claims except 1, 9, 10, 46, and 79.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.



 Examiner's signature, if required

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

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